Benlan™
MED-RX® Oral/Enteral Syringes

JUN 0 3 2014

SECTION 5 - 510(K) SUMMARY

Date of Summary: April 25, 2013

Benlan™

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Official Contact: Cheryl Brown – QA / RA Manager

Proprietary Name:	MED-RX® Oral/Enteral Syringe
Common Name:	Feeding tubes
Classification Name:	Gastrointestinal tubes and accessories
Class:	Class II
Product Code:	KNT
Predicate Device:	BD Oral/Enteral Syringe with BD UniVia Connection (K112434)

Device Description
The MED-RX® Oral/Enteral Syringe is available in two configurations, an enteral tip syringe and an overmolded enteral tip syringe. Both configurations of the MED-RX® Oral/Enteral Syringe are available in various volumes, from 1 to 60mL. All MED-RX® Oral/Enteral Syringe feature graduation markings along the barrel of the syringe, are provided with a tip cap, and are incompatible with standard luer devices. The MED-RX® Oral/Enteral Syringes are provided sterile, and are single use and disposable.

Indications for Use
The MED-RX® Oral/Enteral Syringes are to be used by a healthcare professional to measure and administer oral medication and enteral nutrition. The MED-RX® Oral/Enteral Syringes are sterile, single use, and for pediatric use only.

Substantial Equivalence
The information provided in the premarket notification demonstrates that the proposed device is substantially equivalent to legally marketed devices. The proposed MED-RX® Oral/Enteral Syringes are substantially equivalent to the predicate BD Oral/Enteral Sryinge with BD UniVia Connection (K112434). Both proposed and predicate devices have the same intended use to be used by a healthcare professional to measure and administer oral medication and enteral nutrition. Both the proposed device and the predicate device are manufactured from equivalent materials and feature distinct enteral connectors that are not compatible with luer devices or other small bore non-luer devices. The MED-RX® Oral/Enteral Syringes and the BD Oral/Enteral Sryinge with BD UniVia Connection are single-use, sterile devices, packaged in peelable pouches and sterilized using gamma radiation. There are no significant differences between the

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MED-RX® Oral/Enteral Syringes

proposed MED-RX® Oral/Enteral Syringes and the predicate device, BD Oral/Enteral Sryinge with BD UniVia Connection (K112434). Therefore the proposed device can be considered substantially equivalent to a legally marketed device.

Non-Clinical Test Summary
Verification of functional performance of the MED-RX® Oral/Enteral Syringes has been performed. The MED-RX® Oral/Enteral Syringes were subject to numerous performance tests including device functionality, device compatibility with luer and other small bore non-luer devices, cap resistance to leakage, separation of the cap during typical storage conditions, and for natural rubber latex content. All bench testing was successfully completed on both configurations of the MED-RX® Oral/Enteral Syringe: the overmold enteral tip syringe and the enteral tip syringe.

Summary of Sterilization
Each MED-RX® Patient Delivery Set is individually packaged using a medical grade film pouch and sterilized using gamma radiation to a sterility assurance level of 1×10^{-6}. The radiation dose has been validated as per ANSI/AAMI/ISO 11137-1: 2006.

Summary of Biocompatibility Tests
Biocompatibility testing was successfully completed on sterile finished devices. The MED-RX® Oral/Enteral Syringes are classified as limited duration, mucosal membrane contacting devices. Both configurations of the MED-RX® Oral/Enteral Syringe were tested for biocompatibility. A summary of the testing completed and the relevant standards are listed in Table 1.

Table 1: Biocompatibility Test Summary

Standard	Test Description	Results
ISO 10993-5: 2009	ISO MEM Elution with L-929 Mouse Fibroblast Cells (Cytotoxicity)	Device is considered non-cytotoxic.
ISO 10993-10: 2010	Guinea Pig Maximization Sensitization Test (Method of Biomaterial Extracts)	Device did not elicit a sensitization response.
ISO 10993-10: 2010	Intracutaneous Reactivity Test	The requirements of the test have been met by the test article.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 3, 2014

Benlan, Inc.
Cheryl Brown
Director of Quality Assurance & Regulatory Affairs
2760 Brighton Road
Oakville, Ontario L6H 5T4
Canada

Re: K131183
Trade/Device Name: MED-RX® Oral/Enteral Syringes
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: May 30, 2014
Received: June 3, 2014

Dear Cheryl Brown,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(K) Number (If Known): K131183

Device Name: MED-RX® Oral/Enteral Syringes

Indications For Use:

The MED-RX® Oral/Enteral Syringes are to be used by a healthcare professional to measure and administer oral medication and enteral nutrition. The MED-RX® Oral/Enteral Syringes are sterile, single use, and for pediatric use only.

Prescription Use:	✓	AND/OR	Over-the-Counter Use	N/A
(Part 21 CFR 801 Subpart D)			(21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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